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IN THE

Supreme Court of the United States

October Term, 1967

No. 1374

AN ARTICLE OF DEVICE . . . DIAPULSE MANUFACTURING CORPORATION OF AMERICA,

Petitioner,

against

UNITED STATES OF AMERICA,

Respondent.

TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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Petitioner,

against

UNITED STATES OF AMERICA,

Respondent.

TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit, entered in the above entitled case on January 30, 1968.

Citations to Opinions Below

The Judgment and Ruling on Motion for Order Amending Judgment of the District Court are printed in Appendix A, *infra,* pages 13 and 15, respectively, and are not yet officially reported. The opinion of the Court of Appeals is printed in Appendix A, *infra,* page 20, and is not yet officially reported.

Jurisdiction

The judgment of the Court of Appeals was entered on January 30, 1968 (Appendix A, *infra,* page 20). The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

Questions Presented

1. Whether a forfeiture of property can be decreed on an issue never charged or raised until the Trial Court's charge to the jury.

2. Whether the Trial Court may direct the jury not to rule on all of the issues raised and tried and not to indicate any rulings in favor of petitioner.

3. Whether a finding of falsity, as a fact, of a scientific question of effectiveness, can be made upon the testimony of respondent's own witnesses that the scientific question has not been proven or disproven and is presently the subject of an honest difference of scientific opinion.

4. Whether this Court's decisions in *United States* v. *Urbuteit,* 336 U. S. 804 (1949), and *Kordel* v. *United States,* 335 U. S. 345 (1948) should be changed so as to broaden the statutory definition of labelling in the Federal Food, Drug and Cosmetic Act, 21 U. S. C. §321(m).

Statutes and Regulations Involved

The statutes and regulatory provisions involved are Sections 201(m), 201(n), 304(a)(1) and 502(a) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(m), 321(n), 334(a)(1) and 352(a)], and 21 C. F. R. §1.3. They are printed in Appendix B, *infra,* page 27.

Statement

The instant *in rem* action was brought under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 301 *et seq.*, against a medical device marketed under the trade name of "Diapulse". This device has grown out of diathermy. It is a unit which emits pulsed high-frequency electromagnetic waves to permit medical treatment without the build-up of excessive heat which results in classic diathermy therapy. This device was developed over 25 years ago and has been extensively used throughout the country by professional men and hospitals, including United States Government Veterans Hospitals. Diapulse is marketed to professional men and hospitals and is not promoted to the layman.

The libel of information alleges that the device was misbranded under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 352(a). The libel sets forth 121 issues and charges. In both the libel of information and in respondent's answers to interrogatories, it is basically charged, in each instance, that the labeling for the unit claims that the product is adequate and effective to treat a specific condition, and that this representation is false and misleading on the ground that the article is not adequate and effective for such purpose.

A trial for approximately four weeks ensued, upon these issues, consisting primarily of the testimony and reports of medical witnesses for both sides. Although the issues charged and tried involved the alleged truth or falsity of the specified representations, at the conclusion of the trial, the Trial Court charged the jury that it could find for the respondent if it found that the petitioner failed to disclose in its labeling that there was a difference of opinion among medical experts with respect to any of the named conditions or diseases. This

issue of alleged misbranding had never been raised in the libel of information or in respondent's answers to interrogatories and in fact was first presented at the time of the Trial Court's charge to the jury.

The case was submitted to the jury with a written "Special Verdict Form" which listed each of the diseases and conditions placed in issue by the libel and which instructed the jury to write "yes" before each of the diseases and conditions for which they find false or misleading claims to have been made.

The Trial Court's oral instructions to the jury, however, contradicted the written instructions. The Trial Court instructed the jury that they should not resolve each of the 121 issues raised in the libel and litigated at the trial, and further instructed the jury that they should only indicate findings made in favor of the respondent. The Trial Court refused to instruct or permit the jury to indicate findings in favor of the petitioner.

The jury issued a General Verdict of misbranding against the device and further executed the Special Verdict Form wherein they made affirmative findings in favor of the respondent on 49 of the 121 issues listed.

The District Court issued a judgment finding that the device was misbranded and provided for a relabeling of the device. The Court of Appeals affirmed the judgment and rulings of the District Court.

Reasons for Granting the Writ

Petitioner respectfully submits that certiorari should be granted herein to resolve recurring questions of the interpretation and application of the Federal Food, Drug and Cosmetic Act, which have not been heretofore ruled upon by this Court.

These questions are presented to this Court for the first time. They involve basic questions of the economic regulation of the food, drug and cosmetic industries under the Statute. The very purpose and function of the Statute in its regulation of industry is here in issue. Permeating these issues is a fundamental question of our constitutional protection of due process of law.

I. Petitioner respectfully submits that a recurring and important question of statutory construction, which materially effects prosecutions under the entire Federal Food, Drug and Cosmetic Act, is herein presented for the first time.

The Lower Courts have ruled herein that, as a matter of law, an issue of misbranding under Regulation 21 CFR 1.3 is automatically a part of any case, irrespective of the issues charged in the libel, the issues raised in interrogatories and the issues actually tried. This interpretation is completely at variance with all fundamental concepts of procedural due process of law. It destroys the purpose and function of the complaint and interrogatories to narrow the issues and enable a party to ascertain precisely what he will have to meet at the trial.

Regulation 21 CFR 1.3 provides that the failure to reveal a scientific difference of opinion where there is a *material weight of opinion* contrary to a representation, may render the labeling misleading. This issue was not charged in the libel nor raised in the interrogatories and petitioner was not afforded an opportunity to present evidence on this new issue, which was first raised by the Trial Court after the trial of the action.

There are many questions which would have been relevant if an issue had been presented in this case of a failure to disclose an alleged material difference of

scientific opinion. There would have been a necessary clarification of just what the respondent claimed the petitioner failed to disclose. There would have had to be some fixing of just what it is claimed should have been set forth in the labeling and whether there was a "material weight of opinion contrary" to any particular representation, as set forth in Regulation 21 CFR §1.3. Furthermore, if a particular opinion was not published or otherwise not publicly known there is a very serious question of how a company could conceivably consider such a contrary opinion or report so as to discuss it in its labeling. This question is particularly pertinent in the instant case since none of the respondent's witnesses published any reports or papers contrary to the contentions of petitioner.

The Lower Court's interpretation of the Federal Food, Drug and Cosmetic Act is completely at variance with this Court's ruling in *Cole* v. *Arkansas,* 333 U. S. 196, 201 (1948) where this Court stated:

> "No principle of procedural due process is more clearly established than that notice of the specific charge, and a chance to be heard in a trial of the issues raised by that charge, if desired, are among the constitutional rights of every accused. . . ."

In the instant case, by injecting a new issue after trial, we do not know what the jury really found. We cannot ascertain at this time whether the jury ruled that various representations were false as charged in the libel and answers to interrogatories, or whether the jury ruled that the petitioner failed to disclose in its labeling a difference of scientific opinion with respect to various named conditions and diseases.

This is of particular importance since the very purpose of the Statute is to provide for meaningful regulation

so that a company can abide by the Court's adjudication. The judgment in this case provides for a relabeling of the device. The verdict and judgment do not establish clear and meaningful guidelines for such a relabeling.

The Lower Courts have stated that the purpose of this action is to condemn a product and not to act as a pharmaceutical clearing house.

Petitioner submits that the Courts below have misconstrued the purpose of this regulatory Statute. The Court *is* acting as a pharmaceutical clearing house under the Statute to the extent that it is supposed to rule upon the truth or falsity of claims of efficacy for a product. These are the very issues raised in the complaint and presented for adjudication.

This issue involves the interpretation of the Statute and the effectuation of the very purpose for which this regulatory statute was enacted.

II. The Court of Appeals has ruled, for the first time, that under the Federal Food, Drug and Cosmetic Act it is not necessary to resolve the issues raised by the libel of information and litigated at the trial and has thus introduced a new uncertainty into the economic regulation of the food, drug and cosmetic industries.

The instant complaint placed in issue, the truth or falsity of claims of efficacy allegedly made by petitioner for 121 conditions. Respondent purported to offer proof on each of said issues, and petitioner defended accordingly. The jury was given a Special Verdict Form (Appendix B, *infra*, page 29), and instructed to write a "yes before each of the diseases and conditions for which they found false or misleading claims" had been made. The Trial Court, however, orally instructed the jury that they should not rule on all of the issues. The Trial Court further instructed the jury that they should

mark a "yes" when they made any finding in favor of the respondent and refused to instruct the jury to indicate any findings which they may reach in favor of the petitioner.

The jury issued the Special Verdict Form in which it indicated findings in favor of the respondent with respect to 49 of the issues.

The Court of Appeals ruled that it was not necessary for the jury to resolve all of the issues, since it interpreted 21 U. S. C. 352(a) to mean that if the device was found to be false or misleading *in any one* particular, the purpose of the action to condemn the device would have been fulfilled.

Petitioner submits that this interpretation of 21 U. S. C. 352(a), by the Court of Appeals, is completely at variance with the purpose and function of the Federal Food, Drug and Cosmetic Act to regulate the food, drug and cosmetic industries, and constitutes a denial of procedural due process of law.

The purpose of this action and the section of the Act upon which it is based is not to give a drug a bad name by calling it condemned. Rather, an action is brought in which one unit of the device is seized to provide a *res* so that the Court can adjudicate the issues raised.

Petitioner submits that 21 U. S. C. Section 352(a) is a substantive provision that a device is misbranded if its labeling is false or misleading in any particular. This does not mean, however, that a company should be subjected to a lengthy and costly trial on 121 different issues and, after trial, be denied a resolution of those issues if the jury finds falsity with regard to one particular.

Petitioner submits that it has a right to an adjudication of the issues which were charged and tried. We are

here considering the property rights of a company and the purpose of a regulatory Statute. The petitioner has been subjected to public charges and publicity releases that there are 121 false representations in its literature.

Since this is a medical device which is sold to physicians and hospitals, if any of the claims in the literature are held to be false, those claims must be removed and the literature changed. This is clearly the purpose of the action and the Statute upon which it is founded. We are here considering the economic regulation of the drug industry. The purpose of the action is to resolve the issues and indeed, the judgment itself provides for a relabeling of the device to eliminate objectionable claims.

III. Petitioner respectfully submits that there is a basic question, herein presented of the standard of scientific knowledge and evidence required for prosecutions under the Federal Food, Drug and Cosmetic Act.

In the instant case, the jury was permitted to make a finding of falsity of fact as to a scientific claim of effectiveness, under circumstances where the scientific question has not yet been crystalized into scientific fact, but is rather still in an area of difference of opinion among scientific experts. Cf. *American School of Magnetic Healing* v. *McAnnulty,* 187 U. S. 94 (1902); and *United States* v. *7 Jugs . . . . Dr. Salsbury's Rakos,* 53 F. Supp. 746 (D. Minn. 1944).

This is not a case where a number of experts testify on behalf of each side and the jury may choose to accept the experts of one party rather than the other. We are not dealing with a question of the jury accepting one witness and not another. For the purpose of the issue herein presented, we can completely disregard the mass of evidence and testimony submitted by the petitioner and

consider solely the testimony of the respondent's witnesses.

Petitioner has raised a question of law premised solely upon the testimony of respondent's own witnesses, who clearly admitted that the scientific question of effectiveness has not transcended the realm of difference of opinion into the realm of demonstrable fact.

The scientific question of effectiveness of a product goes through various stages in the crucible of experience. It may begin as a theory, progress to an area of opinion, and thereafter reach the point of demonstrable fact.

It is submitted that a jury cannot make a finding of truth or falsity with respect to the scientific question of the effectiveness of a medical device, where such effectiveness has not as yet been resolved by experience and testing into a fact, but is in that period of its development wherein it is a question of opinion and difference of opinion in the scientific community.

This issue is basic to legal proceedings under the Food, Drug and Cosmetic Act. This issue involves the interpretation and intent of the Statute and the basis upon which legal prosecutions can be predicated.

IV. Petitioner submits that there is a conflict between the rulings of the Courts below and the decisions of this Court in *United States* v. *Urbuteit,* 336 U. S. 804 (1949) and *Kordel* v. *United States,* 335 U. S. 345 (1948).

The Trial Court ruled that the reprints of medical articles in the instant case constitute "labeling", as a matter of law. The only offer of proof on this issue was that the medical articles and the product were both in the premises of a medical practitioner.* This evidence does not constitute the articles as labeling for the device under the decisions of this Court in *United States* v. *Urbuteit, supra,* and *Kordel* v. *United States, supra.*

*] Mr. Marr: Not at this time, your Honor. Your Honor, the Government moves the admission of the material as the material that was on the premises of Dr. Tebbel at the time the device in question was picked up by the Marshal. (Trial Trans. p. 58)

The term "labeling" is a statutory word of art which is defined in the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(m),] as written matter which is upon any article or which "accompanies" such article. In *United States* v. *Urbuteit, supra,* this Court had occasion to consider this section of the Statute and established two elements as necessary to constitute "accompanying" under the Statute. This Court stated:

> "The controlling factors were whether the leaflets were designed for use with the machine and whether they were so used." (336 U. S. at p. 805)

See also *Kordel* v. *United States, supra.*

In the instant case, the Court of Appeals has affirmed the Trial Court's ruling that the medical articles constitute labeling for the device where there has only been an offer of proof with respect to one of the elements laid down by this Court, to wit, the fact that there is a textual relationship between the literature and the device. There was no evidence that the articles were used with the device. There was no evidence of a common origin and common destination of both the articles and the device. In fact, there was no evidence of any kind of the shipment of the articles.

Petitioner does not contend that there need be a simultaneous shipment of the product and the material nor need there be a physical attachment between the literature and the product. Petitioner does contend, however, that not only must there be a textual relationship between the literature and the product, but that there must be some actual use of the literature with the product.

Petitioner respectfully submits that the rulings of the Lower Courts are contrary to the prior rulings of this Court and should be set aside.

Petitioner respectfully submits that these questions should be resolved and that settlement thereof is in the public interest. These questions involve recurring problems of regulation in the Food, Drug and Cosmetic industries. We are considering broad and sweeping rulings involving basic questions of the intent and purpose of the Statute and of our constitutional protection of due process of law.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

MILTON A. BASS,
SOLOMON H. FRIEND,
Attorneys for Petitioner.

Dated: April 26, 1968.

APPENDIX A

Judgment

UNITED STATES DISTRICT COURT

DISTRICT OF CONNECTICUT

ADM. No. 4818

UNITED STATES OF AMERICA,

Libelant,

against

AN ARTICLE OF DEVICE . . . DIAPULSE MANUFACTURING CORPORATION OF AMERICA,

Claimant.

On December 17, 1965, in the United States District Court for the Northern District of Georgia, libel of information was filed against the above-described article. The libel alleges that the article proceeded against is a device and was shipped in interstate commerce and was misbranded when introduced into and while in interstate commerce within the meaning of the Federal Food, Drug, and Cosmetic Act 502(a), 52 Stat. 1050 (1938), 21 U. S. C. 352(a), (1964) in that its labeling, the 16 pieces of printed graphic matter that was seized with the device, contained statements which represent and suggest that the device is adequate and effective for 121 different purposes and uses. The libel further alleges that the labeling is false and misleading since the article is not effective for these purposes or uses.

Pursuant to Monition issued by the United States District Court for the Northern District of Georgia, the United

States Marshal seized the device. Thereafter, Diapulse Corporation of America, a New York corporation, intervened as claimant and answered the libel denying all the material allegations. Upon motion of the claimant the case was removed to this Court for trial. Trial of this action was commenced before this Court at Hartford, Connecticut, on February 21, 1967, and on March 17, 1967, the jury returned a verdict for the libelant; it is therefore hereby

ORDERED, ADJUDGED AND DECREED that the article seized in this action is misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act §502(a), 52 Stat. 1050 (1938), 21 U. S. C. §352(a), (1964), as alleged in the libel of information and pursuant to the Federal Food, Drug, and Cosmetic Act §304(a), 52 Stat. 1044 (1938) as amended, 21 U. S. C. A. §334(a) (Supp. 1967); is condemned and forfeited to the United States of America; and it is further

ORDERED, ADJUDGED AND DECREED that pursuant to the Federal Food, Drug, and Cosmetic Act §304(e), 52 Stat. 1045 (1938), 21 U. S. C. §334(e) (1964), the United States of America shall recover from said claimant court costs and fees and storage and such other proper expenses to be taxed; and it is further

ORDERED, that on or before May 8, 1967, the owner or proper claimant of said device shall show cause why said device shall not be destroyed.

Dated at New Haven, Connecticut, this 31st day of March, 1967.

By the Court:

GILBERT C. EARL,
Clerk, U. S. District Court

Ruling on Motion for Order Amending Judgment

UNITED STATES DISTRICT COURT

DISTRICT OF CONNECTICUT

[SAME TITLE]

In response to this court's Order in its Judgment of March 31, 1967, to show cause why the device, which is the subject matter of said Judgment, should not be destroyed, the Claimant moves for an Order Amending the Judgment heretofore entered in this action in order to provide for an opportunity to relabel the seized article.

It petitions this court that the condemned article be delivered to it pursuant to the Federal Food, Drug, and Cosmetic Act, §304(d), 52 Stat. 1045 (1938), as amended, 21 U. S. C. A. §334(d) (Supp. 1967). The court finding that the Claimant's declared intention to pursue the relabeling procedures constitutes sufficient cause why the said device shall not be forthwith destroyed, it is

ORDERED that said Judgment be amended by adding thereto the following:

ORDERED, ADJUDGED and DECREED that the United States Marshal for this district shall release said article from his custody to the custody of the Claimant for the purpose of bringing the article into compliance with the Federal Food, Drug, and Cosmetic Act, if Claimant, within twenty (20) days from the date of this Decree (a) pays in full the court costs and fees, and storage and other proper expenses of the proceeding herein, and (b) executes

and files with the Clerk of this court a good and sufficient penal bond with surety in the sum of Four Thousand Five Hundred Dollars ($4,500.00), approved by this court, payable to the United States of America, and conditioned on the Claimant's abiding by and performing all the terms and conditions of this Decree and of such further Orders and Decrees as may be entered in this proceeding; and it is further

ORDERED, ADJUDGED and DECREED that

1. After the filing of the bond in this court, the Claimant shall, at its own expense, cause the article to be brought into compliance with the law at a place acceptable to the Department of Health, Education and Welfare, Food and Drug Administration. When the article arrives at this acceptable place, the Claimant shall give written notice to the New York District, Food and Drug Administration, Department of Health, Education and Welfare, New York, New York, that the article has arrived and that the Claimant is prepared to bring the article into compliance with the law under the supervision of a duly authorized representative of the Department of Health, Education and Welfare.

2. The Claimant shall at times, until the article has been released by a duly authorized representative of the Department of Health, Education and Welfare, retain intact the said article for examination or inspection by said representative, and shall maintain the records or other proof necessary to establish the identity of said article to the satisfaction of said representative.

3. The Claimant shall not commence compliance operations until it has received authorization to do so from a

duly authorized representative of the Department of Health, Education and Welfare.

4. The Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of said article until a duly authorized representative of the Department of Health, Education and Welfare shall have had free access thereto in order to take any sample or make any tests or examinations that are deemed necessary, and shall in writing have released such article for shipment, sale, or other disposition.

5. Within ninety (90) days from the date of the filing of the bond in this court, Claimant shall complete the compliance process under the supervision of a duly authorized representative of the Department of Health, Education and Welfare.

6. If Claimant breaches any conditions stated in this Decree, or in any subsequent Decree or Order of this court in this proceeding, Claimant shall return the article immediately to the United States Marshal for this district at Claimant's expense, or shall otherwise dispose of it pursuant to an Order of this court.

7. The Claimant shall not sell or dispose of said article in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State or Territory (as defined in said act) in which they are sold or disposed of.

8. The Claimant shall compensate the United States of America for cost of supervising the relabeling of the seized article at the rate of Eight Dollars ($8.00) per hour per representative for each day actually employed in the

supervision of the compliance process, as salary or wage; where laboratory work is necessary, at the rate of Ten Dollars ($10.00) per hour per person for such laboratory work; where subsistence expenses are incurred, the charge shall be the amount actually paid to the person at a rate not to exceed Sixteen Dollars ($16.00) per day per person for such subsistence expenses. Claimant shall also compensate the United States of America for necessary traveling expenses and for any other necessary expenses which may be incurred in connection with the supervisory responsibilities of said Department of Health, Education and Welfare.

9. If requested by a duly authorized representative of the Department of Health, Education and Welfare, Claimant shall furnish to said representative duplicate copies of invoices of sale of the released article, or shall furnish such other evidence of disposition as said representative may request.

The United States Attorney for this district, on being advised by a duly authorized representative of the Department of Health, Education and Welfare that the conditions of this Decree have been performed, shall transmit such information to the Clerk of this court, whereupon the bond given in this proceeding shall be canceled and discharged; and it is further

ORDERED, ADJUDGED and DECREED that if the Claimant does not avail itself of the opportunity to repossess the condemned article in the manner aforesaid, the United States Marshal for this district shall retain custody of said article pending the issuance of an Order by this court regarding its disposition; and it is further

Ruling on Motion for Order Amending Judgment

ORDERED, ADJUDGED and DECREED that this court expressly retains jurisdiction to issue such further Decrees or Orders as may be necessary to the proper disposition of this proceeding, and that should the Claimant fail to abide by and perform all the terms and conditions of this Decree, or of such further Order or Decree as may be entered in this proceeding, or of said bond, then said bond shall on motion of the United States of America in this proceeding be forfeited and judgment entered thereon; and it is further

ORDERED, ADJUDGED and DECREED that the foregoing Orders added to the Judgment by amendment, which provide for the release of the article under seizure under bond to be brought into compliance under the supervision of the Food and Drug Administration, shall be stayed until time for Claimant to appeal has passed, or if Claimant files an appeal, pending the final disposition of Claimant's appeal.

Dated at Hartford, Connecticut, this 25th day of April, 1967.

M. JOSEPH BLUMENFELD
United States District Judge

Opinion of United States Court of Appeals for the Second Circuit

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 253—September Term, 1967.

(Argued January 9, 1968 Decided January 30, 1968.)

Docket No. 31720

UNITED STATES OF AMERICA,

Libelant-Appellee,

—v.—

AN ARTICLE OF DEVICE . . . DIAPULSE MANUFACTURING CORPORATION OF AMERICA,

Claimant-Appellant.

Before:

SMITH, KAUFMAN and HAYS,

Circuit Judges.

Appeal from judgment of the United States District Court for the District of Connecticut, M. Joseph Blumenfeld, *Judge,* condemning for misbranding a "Diapulse" device under 21 U. S. C. §301 et seq. Affirmed.

MILTON A. BASS, New York, N. Y. (Bass & Friend, New York, N. Y., on the brief), *for claimant-appellant.*

Opinion of United States Court of Appeals

JON O. NEWMAN, United States Attorney, District of Connecticut, Hartford, Conn. (William W. Goodrich, Asst. General Counsel for Food and Drugs, and Charles K. Marr, Attorney, U. S. Department of Health, Education and Welfare, on the brief), *for libelant-appellee.*

SMITH, *Circuit Judge*:

Claimant Diapulse Manufacturing Corporation of America appeals from a judgment entered on a jury verdict March 31, 1967, amended on April 25, 1967 (District Court for the District of Connecticut, M. Joseph Blumenfeld, *Judge*), condemning a "Diapulse" device under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. §301 et seq. We find no error and affirm the judgment.

A Libel of Information filed on December 17, 1965 in the United States District Court for the Northern District of Georgia alleged that the device, a pulsed high frequency generator similar to a conventional diathermy unit but with a lower output, had been shipped in interstate commerce and was misbranded when introduced into and while in interstate commerce within the meaning of 21 U. S. C. §352(a), in that its labeling, 16 pieces of printed and graphic matter seized with the device in the possession of an Atlanta chiropractor, contains statements which represent and suggest that the device is adequate and effective for some 121 different disease and related conditions, which statements are alleged to be false and misleading. After the intervention of the claimant, the action was removed to the District of Connecticut. See 21 U. S. C. §334 (Supp. 1967).

The District Court, in its discretion pursuant to 21 U. S. C. §334(d) (Supp. 1967), gave the claimant an opportunity to relabel the device to bring its labeling within the law, rather than ordering that the device be destroyed.

The appeal is based upon five claims. The first is that since the government's witnesses admitted that there is an honest difference of opinion among medical experts with respect to the issues of effectiveness raised in the libel, there could be no proof that the statements were false in fact. It follows, appellant argues, that the issues should never have been submitted to the jury. Appellant cites *United States* v. *7 Jugs . . . Dr. Salsbury's Rakos,* 53 F. Supp. 746 (D. Min. 1944). That case lends no support to the appellant's argument, for the court there held that where there is shown to be a standard of demonstrable truth, the jury should be allowed to measure the claims of effectiveness which have been made. 53 F. Supp. at 758. As Judge Blumenfeld said in ruling on the motion for judgment notwithstanding the verdict and for a new trial, "In this case, the evidence demonstrated the existence of scientific standards capable of testing the degrees of effectiveness of a product." It was proper to submit the issues to the jury. *Cf. United States* v. *Bottles . . . Jenasol R. J. Formula "60,"* 320 F. 2d 564, 571 (3 Cir. 1963).

Appellant's second claim is that the judgment is defective in making a general finding in favor of the government when, so it is alleged, the jury issued a special verdict in which it found for the appellant on 72 of the 121 issues. Although the form submitted to the jury on which the 121 issues were listed is headed "Special Verdict Form," there was no special verdict in this case. Judge Blumenfeld clearly instructed the jury that if they found one or more false claims of effectiveness, in the labeling, their verdict

should be for the government. He then requested that if their verdict should be for the government, they should write "Yes" in the blank space before each disease, condition, etc. listed on the form as to which they found that false or misleading claims had been made. At another point in the charge he instructed the jury only to pick out those which they thought went to the heart of the government's claims. His reason in doing this was, as he explained, to help prevent the possibility of compromise among the jurors, and to require instead that they reach agreement on at least one claim before finding for the government. The jury returned a general verdict: "In this case the jury finds the issues in favor of the libelant and therefore finds that the device is misbranded." Clearly, the action taken by the court in also requesting the jury to specify some of the claims which it found false or misleading was the submission of special interrogatories, and not a request for a special verdict. Compare Rule 49(a) with Rule 49(b), Federal Rules of Civil Procedure.

Appellant argues that a general judgment in an action such as this destroys its meaning, for the very purpose to be accomplished would appear to be adjudication of each of the 121 issues raised. This misconstrues the purpose of the action, which is to protect consumers from misbranded products and condemn the machine (or drug, etc. as the case may be) if it is found to be misbranded. See *Hipolite Egg Co. v. United States,* 220 U. S. 45, 54-55 (1911); and *United States* v. *Sullivan,* 332 U. S. 689 (1948). 21 U. S. C. §352 provides in relevant part: "A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading *in any particular.*" [Emphasis added.]

Appellant next contends that the Trial Court changed the issues raised by the libel. By picking and choosing

among the sentences constituting the charge to the jury, the appellant asserts that the jury was instructed to find for the government if it found *any* false or misleading claims in the labeling. A fair reading of the whole charge, together with consideration of the special interrogatories, makes it clear that the jury was instructed to confine its attention to the claims specified in the libel, and did so.

It is argued that because there was a general judgment, and it is not clear what the jury specifically found, appellant will not be able to properly relabel its product. As Judge Blumenfeld said: "Claimant mistakes the purpose of a court. It is not a pharmaceutical testing house." Admittedly it would be easier for the claimant in an action such as this to go forward with relabeling its product if the judgment were more specific, but the purpose of the action is simply to condemn the drug, machine, etc. if misbranded (see discussion above), and the action is provided for by statute. The initial determination of the legality of the new labeling is for the administrative body.

It is also claimed that the court changed the issues raised by the libel when it instructed the jury that it could find for the government if it found that there was a difference of opinion among medical experts which was not disclosed in the labeling. Appellant contends that this was a new issue, not raised by the libel or by interrogatories. But this was not a new issue. 21 U. S. C. §321(n) reads:

> If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested . . . but also the extent to which the labeling fails to reveal facts material in the light of such representations or

> material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

This has been read broadly, and not improperly, in 21 C. F. R. §1.3:

> The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Cf. *Research Laboratories, Inc.* v. *United States,* 167 F. 2d 410, 422 (9 Cir. 1948).

Appellant's fourth point is that it was error for the District Court to rule, as a matter of law, that reprints of medical articles constitute "labeling" within the meaning of the statute. It is argued that an article, journal or book does not become labeling for any drug or medical device which a doctor (or chiropractor) may have in his office. That is no doubt true. See *United States* v. *An Undetermined Number of Cases . . . Balanced Foods, Inc.,* 338 F. 2d 157 (2 Cir. 1964), cited by appellant. But the essential question is whether the printed material seized with the device supplements or explains the device—it is the textual relationship, not physical attachment, which is significant. See *Kordel* v. *United States,* 335 U. S. 345 (1948); and *United States* v. *Urbeteit,* 335 U. S. 355 (1948). Here, the claimant admitted distributing all of the material seized with the device. A reprint of a "medical article" need not be treated differently from other printed material alleged to constitute labeling. See *United States* v. *Hoxsey*

Cancer Clinic . . ., 198 F. 2d 273 (5 Cir. 1952), cert. denied 344 U. S. 928 (1953). The "Balanced Foods" case, *supra*, the only authority cited by appellant on this point, involved a store which carried both a mixture of vinegar and honey and a book which misleadingly recommended vinegar and honey as a remedy for various conditions, etc. This court held that there was no evidence of joint promotion of the mixture and the books, and that no inference could be drawn that the books were sold for the purpose of promoting the sale of the mixture. The line is to be drawn, it was held, in terms of the function served by the writing. This is entirely consistent with the holding here.

Appellant's last point is that it was error to allow the introduction of evidence, including opinion testimony, about a medical device called "Theramatic," because that device and appellant's device are not the same. On the evidence adduced, it was not error to hold that the machines were sufficiently similar to allow introduction of evidence as to "Theramatic," for purposes of evaluating "Diapulse".

Judgment affirmed.

APPENDIX B

Statutes and Regulations

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.) provides in pertinent part:

Sec. 201 (m):

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article [21 U. S. C. 321 (m)].

Sec. 201 (n):

If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual [21 U. S. C. 321 (n)].

Sec. 304:

(a) (1) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions

of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . . [21 U. S. C. 334].

Sec. 502 (a):

A drug or device shall be deemed to be misbranded—

If its labeling is false or misleading in any particular [21 U. S. C. 352 (a)].

21 C. F. R. 1.3:

The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Special Verdict Form

UNITED STATES DISTRICT COURT

DISTRICT OF CONNECTICUT

Admiralty No. 4818

[SAME TITLE]

On the three accompanying pages there have been listed those diseases, disorders and conditions for which the government has alleged that false or misleading claims were made by the labelling. In the event your verdict is for the government, write the word "Yes" in the blank space before each of those diseases, disorders and conditions for which you find false or misleading claims were made.

Have each sheet signed by your foreman.

Yes	infections	Yes	rheumatic fever
Yes	otitis media	Yes	Reiter's syndrome
____	Fractures	Yes	hypersplenism
____	bone and tissue healing	Yes	undulant fever
____	smooth muscle spasm, including spasm of the colon	Yes	tuberculosis
		Yes	gonorrhea
		Yes	syphilis
____	bursitis	Yes	tularemia
____	arthritis	Yes	typhoid fever
Yes	low back pain	Yes	serum sickness
Yes	parietal and occipital headaches	Yes	other systemic infections
		____	metabolic disturbances
Yes	systemic disease	Yes	osteoarthritis

Marion Nell
Foreman

Special Verdict Form

Yes	gout
——	radiculitis
——	Paget's disease
——	chronic bleeding
——	intestinal parasitism
——	anemia
——	post-operative wound healing
——	frozen shoulder
——	left ventricular failure
——	bleeding from carcinoma of the cecum
Yes	low back syndrome
——	whiplash syndrome
——	sciatic neuritis
——	rheumatoid arthritis
——	tennis elbow
Yes	pelvic inflammatory disease
——	toxemia
——	spastic colitis
——	agina
——	pyelonephritis
——	ulcerated thrombophlebitis
——	bronchial asthma
——	pilondial cyst
——	sinobronchial disease
——	prostatitis
——	Tonsillar abscess
——	osteomyelitis
——	toxic hepatitis
——	pylorospasm
——	constipation
——	fatigue
——	nervousness
——	anorexia
——	sinus
——	sinusitis and allied conditions
——	lymphadenosis
——	recurrent acute exacerbations
——	thymic enlargements
——	degenerative diseases
Yes	pelvic inflammatory disease complicated by adnexal masses
Yes	abdominal and pelvic pain and tenderness
Yes	diabetes
Yes	diabetic ulcer of the foot
Yes	occlusive vascular disease
——	peripheral neuropathy
Yes	infection of the lower extremity
——	thinning of skin
——	atrophy of muscles
——	loss of subcutaneous fat
——	osteoporosis
Yes	ulceration
Yes	gangrene
Yes	paresthesias in the form of numbness
——	tingling, cold and burning
Yes	ear conditions

Marion Nell
Foreman

Special Verdict Form

——	gynecologic disorders
——	hypertrophic arthritis of spine
——	paranasal sinus with post-nasal drip
——	fungus of the external auditory meatus
Yes	vaginitis
Yes	severe itching
Yes	trichomonas vaginalis
——	peripheral vascular disorders
——	foot ulcers
——	venous stasis ulcer
——	calcified bursitis
Yes	peripheral vascular insufficiency
——	hemiplegia
——	paralysis
——	severe pain in left side of the body rheumatic heart
——	gastric ulcer
——	severe acne
——	chest pain
——	coronary occlusion
Yes	adrenal malfunction
Yes	hypertension and upper respiratory infections in children
Yes	staphylo coccus infection
——	vasospastic and vaso-occlusive disease
——	pneumonia
Yes	septic sore throat
Yes	for the safe treatment of the entire patient
Yes	for stimulating tissue responses and the natural defense mechanisms of the body
Yes	to enhance and stimulate the reticuloendothelial system and for stimulation of the patient's own repair mechanisms which frequently achieve results where other forms of treatment have failed
——	for restoring normal functioning of the joints of the body
Yes	restoring good health
Yes	"Perking up" sick, run-down cells of the body with new life and fresh vigor
Yes	re-energizing the human mechanisms
——	increasing peripheral blood flow without pyrexia
Yes	increasing leucocytes and steroids in the bood without any contraindications
——	devitalizing the pathological focus

Marion Nell
Foreman

Special Verdict Form

Yes stimulation of the liver and spleen

Yes increasing antibody formation

Yes increasing the antigenic reactivity of human gamma globulin

Yes for giving results where all else has failed

Marion Nell
Foreman

In the Supreme Court of the United States

OCTOBER TERM, 1967

No. 1374

AN ARTICLE OF DEVICE . . . DIAPULSE MANUFACTURING CORPORATION OF AMERICA, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. 20-26) is reported at 389 F.2d 612.

JURISDICTION

The judgment of the court of appeals was entered on January 30, 1968. The petition for a writ of certiorari was filed on April 29, 1968. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTES, REGULATION, AND RULE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended (21 U.S.C. 301, *et seq.*), provides in pertinent part:

Section 201(m) (21 U.S.C. 321(m)):

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Section 201(n) (21 U.S.C. 321(n)):

> If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations * * *.

Section 304(a)(1) (21 U.S.C. 334(a)(1) (Supp. II)):

> Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *.

Section 502(a) (21 U.S.C. 352(a)):

> A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

21 C.F.R. 1.3 provides:

> The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Rule 49(b), F. R. Civ. P. provides:

> *General Verdict Accompanied by Answer to Interrogatories.* The court may submit to the jury, together with appropriate forms for a general verdict, written interrogatories upon one or more issues of fact the decision of which is necessary to a verdict. The court shall give such explanation or instruction as may be necessary to enable the jury both to make answers to the interrogatories and to render a general verdict, and the court shall direct the jury both to make written answers and to render a general verdict. When the general verdict and the answers are harmonious, the appropriate judgment upon the verdict and answers shall be entered pursuant to Rule 58. * * *

QUESTIONS PRESENTED

1. Whether issues relating to the effectiveness of the device to treat certain conditions were improperly submitted to the jury, because the government's expert witnesses testified that there was some difference of medical opinion on these issues.

2. Whether the trial court properly instructed the jury that labeling may be misleading if it fails to disclose a material difference of scientific opinion with respect to the truth of its representations.

3. Whether the trial court correctly held, as a matter of law, that the promotional materials seized with the device constituted "labeling."

4. Whether the trial court abused its discretion in the method by which it requested the jury to answer special interrogatories as to the specific claims which it found to be false or misleading.

STATEMENT

On December 17, 1965, the United States filed a Libel of Information in the Northern District of Georgia for condemnation of a "Diapulse" device, alleging that the device (a diathermy or heating unit), shipped in interstate commerce, was misbranded within the meaning of Section 502(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(a). The information also alleged that the device was in the possession of an Atlanta chiropractor and that its labeling (several pieces of printed and graphic matter provided by the manufacturer) contained false and misleading representations that the device was adequate and effective for treating some 121 different diseases and ailments.

After seizure of the device and the printed and graphic materials, Diapulse Manufacturing Corporation of America intervened as claimant, and on its motion the action was removed to the District of Connecticut pursuant to Section 304(a)(1) of the Act, 21

U.S.C. 334(a)(1) (Supp. 1967). On March 17, 1967, a jury returned a verdict that the device was misbranded and answers to special interrogatories setting out 49 respects in which the labeling was found false or misleading (Pet. App. 29-32). Judgment of condemnation was entered but was subsequently modified, pursuant to Section 304(d) of the Act, 21 U.S.C. 334(d) (Supp. 1967), to permit the claimant to relabel the device. The court of appeals affirmed (Pet. App. 20-26).

ARGUMENT

1. Petitioner contends that because government witnesses acknowledged that there was some difference of medical opinion with respect to the issues of effectiveness raised in the libel, these issues should not have been submitted to the jury (Pet. 9-10). As the district court pointed out, however, in ruling on a motion for a new trial (269 F. Supp. 162, 165):

> * * * Witness after witness testified to the existence of bona fide analytic methods by which scientists can determine effectiveness. Laboratory tests were conducted. Control groups were employed. Just as in *Seven Jugs*, "[t]hese tests were recognized by outstanding men of science as constituting conclusive evidence by recognized scientific standards that the remedies were wholly ineffective." 53 F. Supp. 759. * * *

Under petitioner's theory—that the mere fact of a difference of medical opinion renders the issue of misbranding non-justiciable—no libel could be maintained if a claimant could produce one doctor who was

willing to support the claims made. That is clearly an untenable position. Since the government's expert witnesses based their opinions on scientific standards and methods capable of testing the effectiveness of the device, the evidence presented questions of fact which were properly submitted to the jury. See *United States* v. *47 Bottles, More or Less, Etc.*, 320 F.2d 564, 571 (C.A. 3). The evidence amply supports the jury's finding that the device was misbranded.

2. Petitioner contends that the court erred in instructing the jury that labeling may be misleading if it fails to disclose a difference of medical opinion with respect to the truth of its representations. The court emphasized that this issue presents a question whether there were "any significant studies unfavorable to Diapulse" that the company knew or should have known about and did not disclose (R. 2727). While not challenging the instruction as a correct statement of the law, petitioner argues that the absence of a specific allegation in the libel or interrogatories in this respect deprived it of adequate notice (Pet. 5-6).

By operation of the statute and regulations (see pp. 2-3, *supra*), however, the allegation of false and misleading labeling necessarily encompassed this issue. Under the statutory scheme, a libel offers clear warning that the honesty of the labeling is fully to be tested. It is not necessary that the libel spell out in detail every half-truth which may constitute misleading labeling.

The record indicates, moreover, that petitioner was fully aware of the issues comprehended by the allega-

tion of misleading labeling. Counsel argued to the jury at the outset of trial that petitioner had looked to "the work of many scientists" and had "said so when the results did not show up well from a particular scientist." Counsel promised to present "a picture of a company who has taken a machine and given the facts as presented by the physicians to the physicians;" a company that had taken pains to present "a fair, honest, complete presentation of the facts, nothing distorted, not buried, not hidden" (R. 10-11).

3. The written and graphic material which constituted the false and misleading labeling charged in the libel was admitted into evidence without objection (R. 58), and after the government rested, petitioner moved for a directed verdict solely on the ground that the labeling did not make the representations alleged in the libel (R. 1012-1015). Only at the close of all the evidence did petitioner argue that the materials were not labeling (R. 2683).

Contrary to petitioner's contention, the holding of the courts below that the literature constituted "labeling" as a matter of law is not in conflict with this Court's decisions in *Kordel* v. *United States*, 335 U.S. 345, and *United States* v. *Urbuteit*, 336 U.S. 804. Petitioner admitted in its answers to interrogatories and at trial that it had distributed the promotional materials and that they were seized, together with the device, from the premises of a chiropractor to whom it had sold the device. The materials have an obvious "textual relationship" to the device (*Kordel* v. *United States*, *supra*, 335 U.S. at 350), and their obvious and unique purpose was to promote the pur-

chase and use of the device by chiropractors. In these circumstances, where the literature evidently had accomplished its purpose, the fact that it was "used" with the device was established. Compare *United States* v. *47 Bottles, More or Less, Etc.*, *supra*, 320 F.2d at 568-569.

4. The trial court instructed the jury to return a general verdict, either for the government or for the device, and if its verdict was for the government, to indicate on a separate form (Pet. App. 29-32) which of the 121 claims in the labeling it found to be false or misleading. The jury returned a general verdict in favor of the government and found the labeling false or misleading in 49 particulars. Petitioner's objection to this procedure is based on the court's instruction that the jury should specify its findings only as to those claims which it thought were central to the government's case, and that it was not required to answer the interrogatories for all of the 121 claims listed. However, the use of special interrogatories, as well as their form and content, is within the discretion of the trial court. Rule 49(b), Fed. R. Crim. P.; see 5 Moore, *Federal Practice* § 49.04 (2d ed. 1967). The court adopted the interrogatory procedure used here to insure that the jury would rivet its attention upon and actually resolve claims individually, without requiring it to deliberate until the 121 claims were exhausted. This plainly was not an abuse of discretion. As the court of appeals held (Pet. 23), the function of the action was to protect the public from the misbranded device and not to advise the manufacturer of the precise defects in the labeling. The fact

that the court's judgment afforded claimant an opportunity to correct its labeling does not require a different form of verdict.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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